# Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

## Subtitle 20 KIDNEY DISEASE PROGRAM

### Chapter 01 General Regulations

**Authority: Health-General Article, §§13-301—13-315 and 16-204, Annotated Code of Maryland**

## .01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Applicant" means an individual who has applied for, or is in the process of applying for, Kidney Disease Program enrollment and has not yet been certified as an eligible recipient.

(2) "Certification period" means the 12-month period during which an individual is certified as eligible to receive Kidney Disease Program benefits.

(3) "Certified facility" means a hospital, dialysis facility, or transplantation center which the Department certifies meets the standards that the Commission adopts for providing services to recipients and which is certified by Medicare.

(4) "Commission" means the State Commission on Kidney Disease.

(5) "Department" means the State Department of Health and Mental Hygiene.

(6) "Dialysis" means chronic hemodialysis or chronic peritoneal dialysis provided in a certified facility or a facility approved by the Commission or in the patient's home under the auspices of a certified facility or home dialysis program approved by the Commission.

(7) "End stage renal disease (ESRD)" means that stage of renal impairment that appears irreversible and permanent, and requires a regular course of maintenance dialysis or kidney transplantation to maintain life.

(8) "Family" means the recipient and all of the following individuals sharing the same household with the recipient:

(a) The recipient's spouse;

(b) The recipient's natural or adopted children who are younger than 21 years old;

(c) The recipient's natural or adoptive parent, if the recipient is a child younger than 21 years old; and

(d) The recipient's stepchildren or grandchildren for which the recipient has legal or presumed guardianship.

(9) "Liquid assets" means cash or an asset that can readily be converted to cash.

(10) "Medical Assistance" means the State program of comprehensive medical and other health-related care for indigent and medically indigent persons.

(11) "Medicare" means the insurance program administered by the federal government under Title XVIII of the Social Security Act, 42 U.S.C. §1395 et seq.

(12) "Poverty income guidelines" means the federal poverty income guidelines contained in the most recent annual update of the Department of Health and Human Services poverty income guidelines as published in the Federal Register.

(13) "Preauthorization" means an approval required from the Program before services are rendered to a recipient.

(14) "Primary Adult Care Program (PAC)" has the meaning stated in COMAR 10.09.60.02.

(15) "Program" means the Kidney Disease Program of Maryland.

(16) "Program participation fee" means an annual premium which may be assessed by the Program and is based on family income or liquid assets, or both.

(17) "Provider" means an individual, association, partnership, corporation, or unincorporated group licensed or certified to provide health care services for Program recipients.

(18) "Qualified alien" means an alien who:

(a) Has been fully admitted for permanent residence in the United States under the Immigration and Nationality Act (INA);

(b) Has been granted asylum in the United States under §208 of the INA;

(c) Has been admitted into the United States as a refugee under §207 of the INA;

(d) Has been paroled into the United States under §212(d)(5) of the INA for a period of at least 1 year;

(e) Has had deportation withheld under §243(h) of the INA; or

(f) Has been granted conditional entry into the United States under §203(a)(7) of the INA in effect before April 1, 1980.

(19) "Quarterly amount" means the quarterly installment payment which is equal to 25 percent of a recipient's annual Program participation fee.

(20) "Recipient" means an individual who is certified for enrollment in the Kidney Disease Program of Maryland.

(21) "Reimbursable drug list" means the Kidney Disease Program formulary of medications approved for payment.

(22) "Representative" means an individual who, because of an applicant's or a recipient's mental or physical incapacity or youth, or specified dialysis or transplant facility personnel who have been so designated by virtue of the applicant's or recipient's voluntarily signed authorization form, is authorized, in accordance with State law, to complete, sign, or withdraw an application for enrollment in the Program or to activate a hearing process.

(23) Resident.

(a) "Resident" means an individual permanently living in Maryland whose temporary absence from the State does not interrupt continuity of residence.

(b) "Resident" does not mean:

(i) Members or their families, or both, of the United States armed services temporarily stationed in Maryland; or

(ii) Foreign nationals employed in embassies of their native country.

## .02 Program Application Process.

A. A Maryland resident diagnosed with end-stage renal disease may apply for certification with the Program.

B. An applicant, or the applicant's representative, shall complete a written application on the form designated by the Program.

C. Application Supporting Documents.

(1) The Program may require the following as part of the application form or in addition to the application form:

(a) Copies of the previous year's federal income tax return of the applicant and each individual in the applicant's family;

(b) Current statements of liquid assets owned by the applicant and each individual in the applicant's family;

(c) The amount of the current Social Security benefits and all retirement or pension benefits, or both, of the applicant and each individual in the applicant's family;

(d) Documentation of the applicant's identity as well as citizenship or nationality, to the Department's satisfaction, based on federal requirements;

(e) Verification of the applicant's status as a resident of Maryland;

(f) Verification of the applicant's Medicare status;

(g) Verification concerning the applicant's enrollment in any health insurance benefit plan;

(h) Physician's certification that the applicant has ESRD;

(i) Physician's certification that the applicant has begun a regular course of maintenance renal dialysis in a certified facility or received a renal transplant, or both;

(j) A signed statement authorizing the Program to verify, from any source including banks, insurance companies, and public or private agencies providing monetary benefits, information submitted to the Program by the applicant; and

(k) Other information the Program determines is needed to establish whetherthe applicant is eligible to be a recipient.

(2) Refusal to sign an authorization that may be required under §C(1)(j) of this regulation is considered failure to provide sufficient information, and the applicant will be determined ineligible without prejudice in accordance with §F of this regulation.

(3) In reference to §C(1)(a) of this regulation, the Program may accept the previous year's tax return through April 15 of the year in which an application for certification is filed. After April 15, the Program requires the new tax return or proof of extension granted for filing a return.

D. Signature Requirements.

(1) For the purpose of establishing eligibility, the applicant or the applicant's representative, as appropriate, shall complete and sign the application form.

(2) A physician shall sign the certification that the applicant has ESRD and has begun a regular course of maintenance renal dialysis, or has received a renal transplant, or both.

E. The applicant or the applicant's representative shall forward the completed application form and supporting documents to the address designated on the form.

F. An applicant shall provide all required information within 90 days from the date the information is originally requested by the Program or the applicant shall be determined ineligible without prejudice and may reapply.

G. The applicant, or the applicant's representative, may voluntarily withdraw an application at any time without prejudice.

H. If the Program determines that an applicant is not eligible for Program enrollment, the Program shall notify the applicant or the applicant's representative, as appropriate, in writing within 45 days of receipt of a completed application and include the following in the notice:

(1) The basis for the determination of ineligibility;

(2) An explanation of the right to request a hearing; and

(3) A statement that the applicant is permitted to submit a new application for Program enrollment at any time.

I. If the Program determines that an applicant is eligible for Program enrollment, the Program shall:

(1) Establish a certification period in accordance with Regulation .03C of this chapter;

(2) Notify the applicant or the applicant's representative, as appropriate, in writing within 45 days of receipt of a completed application;

(3) Issue a Kidney Disease Program recipient identification card and instructions for using the card; and

(4) Notify the applicant or the applicant's representative, as appropriate, about any Program participation fee due in accordance with Regulation .04 of this chapter.

## .03 Recipient Eligibility and Certification for Program Participation.

A. To be eligible for enrollment in the Program an applicant shall:

(1) Be a resident of Maryland and one of the following:

(a) A citizen of the United States,

(b) A qualified alien, as specified in §C of this regulation, who is eligible in accordance with the requirements related to the 5-year bar specified at §D of this regulation; or

(c) An alien who is:

(i) Eligible for and receiving Supplemental Security Income (SSI);

(ii) A member of a federally recognized Indian tribe, as defined in 25 U.S.C. §450b(e); or

(iii) An American Indian born in Canada to whom §289 of the Immigration and Nationality Act (INA) applies.

(2) Be certified by a physician as having end stage renal disease;

(3) Meet one of the following requirements:

(a) Have begun a regular course of maintenance renal dialysis in a certified facility or have received a renal transplant, or both; or

(b) Have begun a course of maintenance renal dialysis in an out-of-State facility when the Program has preauthorized the treatment based on the facility's proximity to the applicant's residence or to assure continuity of care, or both; and

(4) Submit an application in accordance with Regulation .02 of this chapter.

B. An individual detained by a federal, state, or local penal or correctional system as a result of a charge, indictment, or conviction of a criminal offense is not eligible for Program enrollment.

C. Qualified Aliens. According to §431 of the Personal Responsibility and Work Opportunity and Reconciliation Act of 1996 (PRWORA), qualified aliens admitted to the United States shall include:

(1) The following types of aliens, who may be subject to the 5-year bar specified at §D of this regulation, depending on their most recent date of entry and their date of qualified alien status:

(a) Aliens who were lawfully admitted to the United States for permanent residence or who since admission were granted lawful permanent resident status in accordance with the INA;

(b) Aliens granted parole for at least 1 year under §212(d)(5) of the INA; and

(c) A documented or undocumented immigrant who was battered or subjected to extreme cruelty by the individual's United States citizen or lawful permanent resident spouse or parent, or by a member of the spouse's or parent's family residing in the same household as the immigrant, if:

(i) The spouse or parent consented to, or acquiesced in, the battery or cruelty;

(ii) The abusive act or acts occurred in the United States;

(iii) The individual responsible for the battery or cruelty no longer lives in the same household as the victim;

(iv) A Violence Against Women Act immigration case or a family-based visa petition has been filed; and

(v) There is a substantial connection between the battery or cruelty and the need for Medical Assistance benefits; and

(2) The following types of aliens, who are not subject to the 5-year bar specified in §D of this regulation:

(a) Alien children and pregnant women who are lawfully residing in the United States, including legal permanent residents who have resided in the United States for less than 5 years as described under §214 of the Children's Health Insurance Program Authorization Act of 2009 (CHIPRA);

(b) Aliens who were lawfully admitted to the United States for permanent residence as Amerasian immigrants under §584 of the Foreign Operations, Export Financing and Related Programs Appropriations Act of 1988;

(c) Refugees admitted under §207 of the INA;

(d) Aliens granted asylum under §208 of the INA;

(e) Aliens whose deportation is being withheld under:

(i) §243(h) of the INA as in effect prior to April 1, 1997; or

(ii) §241(b)(3) of the INA, as amended;

(f) Cuban or Haitian entrants, as defined at §501(e) of the Refugee Education Assistance Act of 1980;

(g) Aliens granted conditional entry under §203(a)(7) of the INA in effect before April 1, 1980;

(h) Children receiving federal payments for foster care or adoption assistance under Part B or E of Title IV of the Social Security Act, if the child's foster or adoptive parent is considered a citizen or qualified alien; and

(i) Victims of a severe form of trafficking, in accordance with §107(b)(1) of the Trafficking Victims Protection Act of 2000, who have been subjected to:

(i) Sex trafficking if the act is induced by force, fraud, or coercion, or the individual who was induced to perform the act was younger than 18 years old on the date that the visa application was filed; or

(ii) Involuntary servitude.

D. Five-Year Bar to Program Benefits for Qualified Aliens.

(1) Qualified aliens in the categories specified in §C(1) of this regulation who entered the United States on or after August 22, 1996, were not eligible for Program benefits for 5 years from the date that the qualified alien:

(a) Entered the United States with the status of a qualified alien; or

(b) Obtained the status of a qualified alien, if the individual did not enter the United States as a qualified alien.

(2) The 5-year bar specified in §D(1) of this regulation shall also be applied to qualified aliens who entered the United States before August 22, 1996, but did not remain continuously present in the United States from the last date of entry before August 22, 1996 until the date of qualified alien status.

(3) An alien is not considered to be continuously present in the United States as specified in §D(2) of this regulation if,

before the date of qualified alien status, the alien had:

(a) A single absence from the United States of more than 30 days; or

(b) Absences from the United States totaling more than 90 days.

(4) The 5-year bar to eligibility for Program benefits, specified in §D(1) of this regulation, does not apply to:

(a) Qualified aliens in the categories specified at:

(i) §C(1) of this regulation, who are not subject to the 5-year bar in accordance with §D(1) or (2) of this regulation; or

(ii) §C(2) of this regulation;

(b) A qualified alien who is:

(i) An honorably discharged veteran of the armed forces of the United States;

(ii) On active duty in the armed forces of the United States; or

(iii) The lawfully admitted spouse, including a surviving spouse who has not remarried, or lawfully admitted unmarried dependent child of an honorably discharged veteran or individual on active duty in the armed forces of the United States; and

(c) Lawful permanent residents who:

(i) Entered the United States under another exempt category specified at §D(4)(a)—(b) of this regulation; and

(ii) Converted to lawful permanent resident status.

E. Certification Period.

(1) The Program shall establish the certification period during which an individual is eligible to receive Program benefits.

(2) The certification period shall be retroactive to the first day of maintenance renal dialysis or renal transplantation if a completed application is received by the Program within 30 days after the first day of maintenance renal dialysis, or within 30 days after renal transplantation, whichever treatment occurs first.

(3) If a completed application is received by the Program more than 30 days after the first day of maintenance renal dialysis, or more than 30 days after the date of renal transplantation, whichever treatment occurs first, the certification period shall begin on the first day of the month in which the completed application is received by the Program.

(4) The Program shall certify a recipient for a 12-month period.

(5) The Program shall promptly redetermine eligibility when it receives information concerning a recipient's circumstances that may affect continuing eligibility.

F. A recipient shall comply with the following requirements to continue Program enrollment throughout a certification period:

(1) Unless a recipient can document continuing insurance coverage that is equal to or greater than Medicare benefits, apply for enrollment in Part A, Part B, and Part D of Medicare within 60 days of notification to do so by the Program, if not already a Medicare beneficiary;

(2) Apply for enrollment in Part A, Part B, and Part D of Medicare within 60 days following termination of insurance coverage that is equal to or greater than Medicare benefits;

(3) Maintain enrollment in Part A, Part B, and Part D of Medicare if eligible;

(4) Apply for enrollment in Medical Assistance within 60 days of notification to do so by the Program;

(5) Maintain enrollment in Medical Assistance if eligible;

(6) Continue to meet the requirements of §§A and I of this regulation;

(7) Reimburse the Department any monies received from any insurance company or other third party for payment of ESRD treatment costs previously reimbursed by the Program; and

(8) Pay the Program participation fee, if applicable, in accordance with Regulation .04 of this chapter.

G. A recipient is considered to have failed to meet the requirement of §F(4) of this regulation if:

(1) The recipient fails to provide information required for certification or recertification of Medical Assistance eligibility; or

(2) Medical Assistance disenrolls the recipient because of recipient fraud, recipient abuse, or recipient failure to comply with reporting requirements.

H. Reapplication for Continuation of Certification.

(1) The Program shall notify the recipient in writing 60 days before an annual certification period expires.

(2) A recipient shall complete a written application for continuation of certification for Program benefits.

(3) A recipient shall be disenrolled from the Program upon expiration of a certification period unless the Program receives a completed application for continuation of certification 30 days before expiration of a certification period.

I. The recipient shall notify the Program within 30 working days of:

(1) A payment received from any source that is related to treatment of the recipient's ESRD;

(2) The recipient's regaining renal function;

(3) A change in address; or

(4) A change in State residence, citizenship, or alien status.

J. Termination Before Expiration of Certification Period.

(1) The Program shall terminate a recipient's enrollment in the Program before expiration of the current certification period if the recipient:

(a) Fails to provide the notice required by §I of this regulation;

(b) Voluntarily disenrolls;

(c) No longer meets the medical requirements for participation;

(d) No longer meets the residence, citizenship, or alien status requirements of §A(1) of this regulation;

(e) Fails to pay the Program participation fee described in Regulation .04 of this chapter;

(f) Fails to apply for and maintain enrollment in Medicare, if eligible;

(g) Fails to apply for and maintain enrollment in the Medical Assistance Program if required by the Program;

(h) Fails to pay the Department any monies received from any source for payment of ESRD treatment costs previously reimbursed by the Program;

(i) Has not received a kidney transplant but no longer requires a regular course of maintenance dialysis, 12 months after the date on which the course of dialysis is terminated;

(j) Is incarcerated by a federal, state, or local penal or correctional system;

(k) Has used the Program identification number to fraudulently obtain goods or services, or permits another individual to use the Program identification number to fraudulently obtain goods or services;

(l) Fails to pay the quarterly amount within the required time frame and the Program has not paid for any services provided for the recipient within the quarter; or

(m) Has died.

(2) Pursuant to §J(1)(l) of this regulation, termination is considered voluntary withdrawal and becomes effective retroactive to the first day of the quarter billed.

K. Continuing Certification and Termination Notices.

(1) The Program shall inform a recipient, or the recipient's representative, of the recipient's rights and obligations regarding continuing certification and termination of Program enrollment.

(2) The Program shall give the recipient or the recipient's representative written notification of the following:

(a) That a certification period is due to expire and reapplication is required as set forth in §H of this regulation;

(b) The effective date of termination of Program enrollment when:

(i) The recipient no longer meets the residence, citizenship, or alien status requirements,

(ii) The recipient is incarcerated, or

(iii) The recipient has died; and

(c) The Program's intent to terminate the recipient's enrollment for reasons other than those set forth in §K(2)(a) and (b) of this regulation.

(3) A notice that the certification period is about to expire or of the Program's intent to terminate the recipient's enrollment due to the recipient's failure to apply for recertification or to pay the assessed quarterly premium shall:

(a) Be mailed at least 30 calendar days before the date on which the action is to be effective;

(b) Include a statement of the proposed actions, the reasons for the action, and the regulatory citation supporting the action; and

(c) Include an explanation of the right to request a hearing.

L. If the Program determines that the recipient has used the Program identification number to fraudulently obtain goods or services, or has permitted another individual to use the Program identification number to fraudulently obtain goods or services, and certification is terminated pursuant to §J(1)(k) of this regulation, the recipient is not eligible to reapply for Program certification.

*10.20.01.04*

## .04 Program Participation Fee.

A. A recipient whose family income exceeds 175 percent of the poverty income guidelines or whose family liquid assets exceed 200 percent of the poverty income guidelines, or both, at the time of initial application or reapplication is required to pay an annual Program participation fee.

B. Family income for purposes of this regulation includes the adjusted gross income, as defined in the Internal Revenue Code for federal income tax purposes, plus Social Security benefits, all pension or retirement benefits, or both, and all interest income not otherwise included in the adjusted gross income for federal income tax purposes, of the recipient and each person in the recipient's family.

C. The Program shall establish a recipient's annual Program payment fee equal to the sum of:

(1) 5 percent of the amount by which the family income exceeds 175 percent of the poverty income guidelines adjusted for family size; plus

(2) 5 percent of the family's liquid assets above 200 percent of the poverty income guidelines adjusted for family size.

D. For purposes of §C(2) of this regulation, the Program shall:

(1) Include assets which are available as of the date of application for initial enrollment or certification of continuing enrollment, as applicable, in the family's liquid assets;

(2) Include the following in the family's liquid assets:

(a) Cash,

(b) Savings and checking accounts,

(c) Certificates of deposit,

(d) Stocks,

(e) Bonds,

(f) Life insurance cash value exceeding $1,500,

(g) Mutual funds,

(h) Money market certificates, and

(i) Other financial instruments or investments that can readily be converted to cash; and

(3) Exclude the following from the family's liquid assets:

(a) Items of real property, and

(b) Items of personal property.

E. Collection of Fees.

(1) The Department shall collect the annual Program participation fee in quarterly installments.

(2) The Program shall notify the recipient of the amount of the annual Program participation fee, the quarterly amount to be paid, the payment due date, and payment procedures.

(3) The Program may revise the amount of the Program participation fee during a certification period if the Program determines that a revision should be made because of a change in:

(a) Family income;

(b) Family liquid assets; or

(c) Composition of the family unit.

(4) The recipient shall have a grace period lasting from the first day of the quarter until 30 days before the end of the quarter in which to pay the quarterly amount.

(5) The recipient's enrollment in the Program shall be terminated on the last day of the quarter if a fee amount is not paid by the end of the grace period.

(6) The recipient is responsible for the assessed quarterly amount if the Program receives claims and makes payment for services provided for the recipient within the quarterly billing period.

(7) The Program shall extend the grace period for up to 6 months when the Program determines that, due to extraordinary medical expenses paid by the recipient, a change in family income, or frequent or extended hospitalizations, payment within the grace period will cause substantial hardship to the recipient.

(9) Before the Program will recertify an applicant whose prior Program enrollment was terminated for failure to pay the Program participation fee in accordance with this regulation, the applicant shall:

(a) Pay any unpaid fees owing for all prior enrollment periods during which the applicant was enrolled in the Program; and

(b) Make advance payment of the first quarterly installment of the Program participation fee established for the subsequent enrollment period.

## .05 Preauthorization.

A. The following procedures or services require preauthorization:

(1) Treatment that is provided outside of Maryland;

(2) Pre-renal transplant dental services;

(3) Ancillary supplies for home intravenous antibiotic therapy;

(4) Durable medical equipment and disposable medical supplies used in the home; and

(5) One pair of eyeglasses, one time only.

B. The Program may preauthorize services when the provider submits to the Program adequate documentation demonstrating that the service to be preauthorized is directly related to treatment of the recipient's ESRD.

C. Renal transplantation services provided to a recipient outside of Maryland are not eligible for reimbursement unless the Commission gives prior written approval for the transplant.

D. The Program does not cover:

(1) Any service denied by Medicare as not medically justified or any services covered by Medical Assistance; or

(2) Services which are investigational or experimental.

E. In cases of multiple organ transplants, Program coverage shall be limited to only those services related to transplantation of the kidney. The provider shall break out and satisfactorily document the charges related to the kidney transplant before submitting a reimbursement request to the Program.

*10.20.01.06*

## .06 License Requirements.

A. A pharmacy may not qualify as a provider without first having obtained a permit from the Department pursuant to Health Occupations Article, Title 12, Annotated Code of Maryland, or from the appropriate agency in the state in which the pharmacy is located.

B. A pharmacy that provides compounded prescriptions for home intravenous therapy shall be licensed under the provisions of COMAR 10.34.19.

C. A doctor of medicine or osteopathy shall be licensed and legally authorized to practice medicine and surgery, and to dispense drugs in the state in which the service is provided.

## .07 Provider Reimbursement.

A. To qualify as a provider, a pharmacy shall:

(1) Maintain a permit from the Department pursuant to Health Occupations Article, Title 12, Annotated Code of Maryland, or from the appropriate agency in the state in which the pharmacy is located;

(2) To the extent required by law, be licensed and legally authorized to practice or deliver services in the state in which the service is provided; and

(3) Be a provider in the Maryland Medical Assistance Program.

B. The Program shall reimburse for treatment directly related to a recipient's ESRD or a condition that is a direct result of the recipient's ESRD.

C. The Program shall reimburse the incurred costs of prescription drugs and other pharmaceutical products determined to be medically necessary by the recipient's physician for treatment directly related to the recipient's ESRD or a condition that is a direct result of the recipient's ESRD.

D. Before invoicing the Program, providers of Program-approved services shall first seek reimbursement from all other payment sources of the recipient including, but not limited to, insurance coverage, Medicare, Medical Assistance, and PAC. If the other sources reject a claim or pay less than the amount allowed by the Program, the provider may then submit the claim to the Program for review.

E. A pharmacy provider may invoice the Program for reimbursement of legend drugs covered through the major medical component of a recipient's third-party insurance. The Program shall then seek reimbursement from the recipient's major medical coverage.

F. When a recipient who is a Medicare beneficiary is provided a service that is covered by Medicare and the Program, Program payment shall be limited to payment of the recipient's Medicare deductible and co-insurance amounts.

G. The Program may not reimburse for Medical Assistance covered services if the recipient is a Medical Assistance recipient.

H. When a service is covered by a recipient's health insurance plan under which the provider agrees to accept payment by the health insurance plan as payment in full for the service, payment may not be made by the Program.

I. The Program may not make a direct payment to a recipient.

J. Program reimbursement for outpatient dialysis treatment shall be consistent with the limits established and rates paid by Medicare.

K. Program reimbursement for other than outpatient dialysis treatment shall be consistent with the limits established and rates or fees paid by the Maryland Medical Assistance Program for the service except as otherwise indicated in this regulation. For services reimbursed on a fee basis, only the Medical Assistance net reimbursement amount will be paid.

L. Reimbursement for preauthorized out-of-State renal transplantation services may not exceed rates paid for the same or similar services in Maryland.

M. Program reimbursement for pharmacy services is as follows:

(1) The Program shall only pay for legend drugs and diabetic supplies itemized on the Kidney Disease Program of Maryland Reimbursable Drug List;

(2) A pharmacy provider shall charge the Program the provider's usual and customary charge to the general public for legend drugs;

(3) Drugs shall be reimbursed by the Program as follows:

(a) Program payment for a legend drug shall be the lower of the provider's charge or the Medical Assistance allowable cost for the drug;

(b) In addition to payment for the legend drug ingredient cost, the Program shall establish and pay a dispensing fee for legend drugs;

(c) Duration of coverage for immunosuppressant drugs shall be consistent with Medicare policy;

(d) The Program shall only pay for a generic equivalent unless a brand is specified as medically necessary by the prescribing physician;

(e) The Program may not pay for more than a 34-day supply of an approved drug during a 26-day period;

(f) The Program may not pay for replacement of lost medications;

(g) The Program may pay for replacement of stolen medications when the claim is accompanied by a police report;

(h) A pharmacy provider shall maintain on file a hard copy of each prescription filled for a recipient; and

(i) The Program may not pay for legend drugs which are not FDA approved for the prescribed usage or which the FDA has declared to be "less-than-effective".

N. Reimbursement for Epogen (Epoetin alfa), dispensed as part of the dialysis procedure, shall be consistent with Medicare rates. Reimbursement shall be limited to dialysis facilities.

O. Reimbursement for Procrit (Epoetin alfa) shall be consistent with Medicare rates. Coverage is limited to active renal transplant recipients.

P. The Program shall provide reimbursement for access surgery required by a recipient for dialysis treatment even though the access surgery may predate the recipient's date of certification for Program benefits as established in accordance with Regulation .03 of this chapter.

Q. To receive reimbursement from the Program a provider shall:

(1) Accept payment by the Program as payment in full and make no additional charge to any person for services covered by the Program;

(2) Provide services without regard to race, color, age, sex, national origin, marital status, or physical or mental handicap;

(3) Verify the recipient's Program eligibility each time a service is provided by viewing the recipient's Kidney Disease Program identification card with a valid through date;

(4) Notify the Program immediately of any recipient or provider activity or circumstance that affects eligibility, benefits, or reimbursement;

(5) Maintain the confidentiality of all recipient information;

(6) Submit the request for payment for services rendered according to procedures established by the Program and in the form designated by the Program; and

(7) Maintain and make available administrative and medical records in accordance with the following requirements:

(a) Administrative and medical records shall contain documentation that is sufficient in quantity, scope, and detail to confirm that services are provided in accordance with this chapter;

(b) Records shall be maintained for a minimum of 6 years; and

(c) Records shall be made available on request to the Department or the Department's designee.

## .08 Limitations.

A. The Program does not cover a drug if:

(1) The manufacturer has not provided the same rebate to the Kidney Disease Program as that provided for State-Only Pharmacy Assistance recipients' purchases of drugs as is required under §1927(c) of Title XIX of the Social Security Act (42 U.S.C. §1396r-8(c));

(2) The Program has provided notice to the manufacturer of the manufacturer's failure to provide adequate rebates and its opportunity to request a waiver from the rebate requirement under §A(3) of this regulation; and

(3) The manufacturer has failed to demonstrate to the Secretary that the drug's availability is essential to Kidney Disease Program recipients.

B. Effective April 4, 2012, a manufacturer or its designee may not dispute or request repayment of any rebate paid under §A(1) of this regulation more than 1 year after the date the rebate was paid.

## .09 Payment Procedures.

A. A provider shall submit the request for Program payment for services rendered to a recipient according to procedures established by the Program and in the form designated by the Program.

B. The Program reserves the right to return to the provider, before payment, all invoices not properly signed, completed, and accompanied by properly completed forms required by the Program.

C. Billing Time Limits.

(1) The Program may not make payments for an invoice that the Program receives more than 6 months from the date of service, except for an invoice first submitted to Medicare, a health insurer, or other third party for reimbursement.

(2) For an invoice initially submitted to a third party for payment, the Program may not make payment unless the Program receives the invoice within 6 months of the date of service or 3 months of the third party's notification of payment action to the provider, whichever is later.

(3) The Program shall make payment on a claim which the Program returns to the provider due to improper completion or incomplete information only if the claim is properly completed, resubmitted, and received by the Program within the original 6 months, or within 3 months of being returned, whichever is later.

(4) If Medicare, or a third party rejects a provider's claim because the claim was not received within the third party's billing time limits, the Program may not make payment on that claim.

(5) If the Program denies payment due to late billing, a provider may not recover the amount later from either the recipient or the Department.

*10.20.01.10*

## .10 Informal Reconsiderations and Hearings.

A. Informal Reconsideration.

(1) An applicant, recipient, or provider dissatisfied with a decision, action, or inaction of the Department under this chapter shall be granted an opportunity for an informal reconsideration of the matter.

(2) The informal reconsideration shall include:

(a) Written notice to the applicant, recipient, or provider of the decision or action taken by the Department and the basis for the decision or action;

(b) If applicable, a written description of the basis for the Department's inaction;

(c) A reasonable opportunity for the applicant, recipient, or provider to refute the basis of the Department's decision, action, or inaction; and

(d) A written affirmation or reversal of the Department's decision, action, or inaction.

(3) The opportunity to refute the Department's decision, action, or inaction specified in §A(2)(c) of this regulation may be provided:

(a) In a meeting with a representative of the Program at the offices of the Program;

(b) By telephone conference; or

(c) In writing.

B. Hearings.

(1) The Department shall grant an opportunity for a hearing to an applicant or recipient who:

(a) Is determined to be ineligible for benefits under the Program;

(b) Is terminated from enrollment in the Program; or

(c) Is otherwise denied benefits under the Program due to a decision, action, or inaction of the Department.

(2) An applicant or recipient requesting a hearing shall notify the Department of the request within 30 days of the date of receipt of the notice of final decision or intended action by the Department.

(3) Hearings shall be conducted in accordance with COMAR 10.01.03.

*10.20.01.11*

## .11 Program Recovery and Reimbursement.

A. The Department shall seek recovery in all cases when Program benefits have been incorrectly paid.

B. The Department shall accept reimbursement when voluntarily offered by a current or former recipient or someone acting on the recipient's behalf.

C. The Department may institute any proceedings that the Department considers necessary to require collection of uncollected fees.

D. The Program shall refer to the Central Collection Unit in the Department of Budget and Fiscal Planning for investigation and other appropriate action all cases in which a recipient has received coverage erroneously as a result of the action or inaction of the recipient.

E. The Department shall investigate and take appropriate action in all cases in which eligibility has been incorrectly established as a result of the action or inaction of a recipient, representative, or person acting responsibly for the recipient.

F. The Program shall require a recipient to authorize the release to the Department of all data, records, and information by insurance companies, nonprofit health service plans, providers of medical care, employers, unions, governmental agencies, and any other agencies, organizations, or individuals necessary for the Department's pursuit of third-party reimbursement. The authorization extends to all information relevant to third-party reimbursement or third-party health care coverage.

G. The Department shall collect available benefits from third parties determined liable to pay for services received under the Program.

H. A recipient who receives medical services that were or will be paid for by the Program is considered to have made assignment to the Department of the:

(1) Recipient's rights to any third-party payments for medical care; and

(2) Rights of any other individual eligible under the plan, for whom the recipient can legally make an assignment.

I. The assignment created under §H of this regulation shall be effective as long as the recipient is enrolled in the Program and remains effective for all services paid by the Program during this period of enrollment, and for those services which were erroneously provided to ineligible persons and paid for by the Program.

J. If a recipient dies, the Department may make a claim against the estate of the recipient for any unpaid fee established for that recipient in accordance with the following:

(1) Except as provided in §J(4) of this regulation, a claim shall not be made for any fee for services provided more than 3 years before the recipient died;

(2) A claim under this section is a preferred claim against the estate of a deceased recipient;

(3) The claim may be waived by the Department if, in the Department's judgment, enforcement of the claim will cause substantial hardship to dependents of the deceased; and

(4) If a responsible relative who is liable for the cost of care of the recipient has misrepresented assets or submitted fraudulent information and, by doing so, has avoided any part of the claim for the cost of care, there is no limitation on the time in which the claim may be brought against the estate.

*10.20.01.12*

## .12 Conflict with Regulations of the Kidney Disease Commission.

Pursuant to Health-General Article, §13-308(e), Annotated Code of Maryland, the Department is authorized, after consulting with the Commission, to adopt these regulations. Accordingly, these regulations supersede any regulations issued by the Commission that concern nonmedical issues.